BRS Stakeholder Update

Winter 2006-2007

Message from the Deputy Administrator

Happy New Year! I would like to take this opportunity to provide another Stakeholder Update from Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). BRS had a busy year in 2006 and is looking forward to all of the work to be done in 2007. As we start the new year, I would like to take a moment to reflect on the hard work done by BRS staff in 2006.

We continue to see a rise in the number of applications and petitions processed, with a 14% increase in permits, a 2% increase in notifications, and a 100% increase in petitions processed by BRS from 2005 to 2006. In addition, there is a greater complexity to the review process due to the rising number of genes being submitted on each individual application. As a result of increased work loads and a greater complexity in the science, BRS continues to identify and implement processes, procedures, and system improvements that are results driven and impact program effectiveness, efficiency, and credibility in a positive manner. For example, BRS:

- Consolidated all permit and notification applications and related information into a single, fully-integrated system, thereby reducing cost and management burdens.
- Developed and implemented a controlled work flow on all notifications and permits to improve the quality of work performed, streamline processes, and provide management resources and intelligence to assist with performance measures, metrics, and accountability.
- Developed and implemented an electronic web-based on-line permitting system, ePermits, allowing applicants to conduct processes online and providing an automated platform for state reviews and comments on BRS applications.
- Improved information security and integrity for all of its electronic data and implemented tools to allow for recovery of information.
- Improved and strengthened its regulatory review process by incorporating more thorough and comprehensive documentation in all scientific risk analysis and reviews, such as a National Environmental Policy Act (NEPA) decision summary and inclusion of more discussion of threatened, endangered, and sensitive species (TES) analysis in state letters.
- Established a program document repository including standard operating procedures to leverage and ensure best practices.

As you can see, if 2006 is any indication, 2007 will be a very busy year for BRS. We hope you find this stakeholder update informative, and encourage you to visit our Web site (http://www.aphis.usda.gov/brs) for the latest news and information.

If you have not previously registered with our on-line BRS stakeholder registry, please go to https://web01.aphis.usda.gov/BRS/BRSWeb.nsf and sign up to ensure that you receive all future stakeholder updates.

Sincerely,

Cindy Smith
BRS Deputy Administrator

Update on GE Rice

As we mentioned in the Summer 2006 BRS Stakeholder Update, Bayer CropScience notified USDA and the U.S. Food and Drug Administration (FDA) on July 31, 2006, that the company had detected trace amounts of a regulated genetically engineered (GE) rice (LLRICE601) in commercial long-grain rice. USDA and FDA both reviewed the available scientific data and concluded that there are no human health, food safety, or environmental concerns associated with this GE rice. An APHIS investigation to determine the circumstances surrounding the release and whether any USDA regulations were violated is nearly complete, and we will provide details on the results of the investigation once it is finalized.

Testing Results Announced

On November 24, APHIS announced that tests have identified 2003 Cheniere variety as the only foundation seed that tested positive for LLRICE601. The tests were conducted as part of our ongoing investigation of the release of LLRICE601. In addition, tests of a separate sample of the 2003 Cheniere variety indicate the presence of trace levels of LLRICE62, a line of GE rice also developed by Bayer Crop Science. Since LLRICE62 was deregulated by APHIS in 1999, this rice line is not the focus of APHIS' investigation. LLRICE62 has already undergone a food safety evaluation by FDA and has been determined to present no safety concerns. While it is APHIS policy not to disclose results of an inquiry until a full investigation is complete, this information was made available to assist farmers in making decisions in preparation for the 2007 planting season and to inform trading partners as part of the Agency's commitment to transparency.

Deregulation of LLRICE601

On November 24, APHIS announced that after a thorough review of scientific evidence, the Agency would deregulate LLRICE601 based on the fact that it is as safe as its traditionally bred counterparts. The final environmental assessment (EA) was published in the *Federal Register* on December 4. APHIS initiated the process after Bayer submitted a petition to deregulate LLRICE601. The process included a request for public comment, which was published in the *Federal Register* on September 8. APHIS deregulated two similar LibertyLink rice lines, LLRICE62 and LLRICE06, in 1999 after thorough safety evaluations and is extending its deregulation of the original two lines to include LLRICE601. This protein has been scientifically reviewed and approved for use in a dozen countries around the world. Documents related to this subject, including the EA, are posted on the BRS website at http://www.aphis.usda.gov/brs/brs_notices.html.

Codex Adopts U.S. Proposal on Food Safety Risk Assessments of Foods Derived from GE Plants

During the last week in November, BRS Deputy Administrator Cindy Smith participated in the meeting of the Codex Alimentarius' Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology in Chiba, Japan. The United States had worked for several months to raise international support for its food safety risk assessment proposal for the inadvertent, low-level presence of GE products in food. The task force adopted the U.S. proposal and created a working group to be chaired by the United States, Germany, and Thailand, that will draft an annex to the "Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants." The annex will cover the elements of a safety assessment for the low-level presence of GE material in food, and identify information-sharing mechanisms to assist importing countries in conducting food safety assessments. The first meeting of the

working group will be held in the United States early next year. BRS is pleased that the U.S. proposal was adopted, and looks forward to addressing the low-level presence of regulated materials through an international dialogue.

ePermits News

As part of USDA's overall eGovernment initiative to transform and enhance the delivery of its programs, services, and information, BRS has now extended its ePermits system to allow applicants to submit permit applications electronically and to allow States to review notifications and permits online. We think the ability to apply for permits online will be a great benefit to our customers, as evidenced by the implementation of electronic submission of notifications, which became available in May 2006. Since then, over 90% of our applicants have submitted notifications through ePermits.

We encourage all of our applicants to apply for notifications and permits using ePermits. In addition to the ease of applying on-line, the ePermits system has other time-saving features such as an individual ePermits workspace, tools to help generate new applications from previous submissions and to create Confidential Business Information (CBI)-deleted versions of an application, and the ability to add attachments to permit applications. To be able to use all features of the ePermits system, applicants must have Level 2 access, which requires independent verification of their identity and can be obtained through the eAuthentication process. However, as an interim measure to aid BRS applicants in taking advantage of this system, BRS is allowing applicants to submit applications through ePermits with only Level 1 access, which is available immediately upon completing the on-line application. To obtain either Level 1 or Level 2 access, please visit: http://www.eauth.egov.usda.gov/eauthWhatIsAccount.html. Until Level 2 access is acquired, applicants must print their submitted application and mail a signed and dated copy to BRS.

Another new feature of the ePermits system allows States to review all notifications and permits electronically. Each State will have its own mailbox and State officials who have been eAuthenticated will receive email notification when new notifications and permits arrive for review or when notifications are acknowledged or permits are issued. The ePermits system will store all notification and permit information that has been sent to the mailboxes, allowing States to have easy access to this important information while reducing email traffic.

USDA Advisory Committee Issues Consensus Report

On August 30, USDA's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) issued a consensus report about the future of biotechnology titled, "Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead." The report describes the advances in agricultural biotechnology's first decade and discusses a range of topics related to agricultural biotechnology that may be addressed by the Secretary of Agriculture over the next decade. The AC21 was established in 2003 to examine how biotechnology is likely to change agriculture and USDA's work over the long term. The 20-member committee represents a wide spectrum of views and interests and is composed of farmers, technology providers, academics, representatives from the food manufacturing and shipping industries, and representatives from consumer and environmental organizations. The committee meets in public session three to four times per year. To view the report and for more information about the AC21, please visit: http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=AC21Reports.xml.

BRS Employee Spotlight: Dr. Levis (Lee) Handley

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

Position: Senior Biotechnologist, Plants Branch, Environmental Risk Analysis Program

Years with BRS: Three—I joined BRS in December 2003.

Activities prior to joining BRS: After receiving my Ph.D., I was a post-doctoral associate at Michigan State University for two years working in the Department of Horticulture. I developed somatic hybrids between tomato and *Solanum lycopersicoides*, a wild species of nightshade native to Chile and Peru, in an attempt to transfer cold tolerance from this species into commercial tomato. I then joined a company in South Carolina, where I worked in the area of forest tree biotechnology for 18 years, with species such as pine, cottonwood, and eucalyptus.

Education: I have B.S. and M.S. degrees in Horticulture from Auburn University, and a Ph.D. in Horticultural Science from North Carolina State University. My M.S. degree was in plant breeding and my Ph.D. focused on plant physiology.

Job Description: My primary job responsibility is to conduct biological risk assessments of genetically engineered plants for both field testing as well as for deregulation. In addition, I serve on the ePermits development team for BRS.

Proudest Accomplishment: Prior to joining BRS - being the inventor and co-inventor on nine patents in the area of plant biotechnology. Since joining BRS - being involved in the development of ePermits and seeing it come to fruition. It has been very exciting to see something that took months and months to develop start to take off. The positive feedback we have received from applicants and staff has been very rewarding. When you are involved in a project like this you sometimes wonder if it will actually work as you are developing it. And then you are surprised at how well it does work once you've launched it!

What motivates you about your job: I like the diversity of work. BRS is an exciting mix of biology, policy, and politics. My interests are very diverse and my job lets me tap into my practical training in agriculture as well as my background in biotechnology. I am very detail oriented and the job lends itself to this. I'm able to use my background in agriculture and biology when conducting risk assessments and writing detailed environmental assessments. Detail is also important in the development of a system like ePermits where every aspect of applying for a permit or notification, and the workflow that comes afterwards, has to be captured at a precise level. In addition, I'm always learning on the job, which satisfies the scientist in me.

Administrative Update

Cindy Eck, who has been with APHIS for 14 years, joined BRS as the new Document Control Officer. Cindy has worked with BRS in the past as a Freedom of Information Act (FOIA) Program Specialist/Information Analyst and a Public Affairs Specialist that supported the mission of our former Biotechnology, Biologics and Environmental Protection Staff. In her new role, Cindy manages and oversees BRS program records and information needs.

Tracy Dukes joined the BRS staff in November as the staff assistant for the Compliance & Inspection Branch. Tracy comes to BRS from APHIS' Plant Protection and Quarantine program. Tracy provides information, administrative, and technical support for the program.

Two new Biotechnologists joined the BRS Environmental Risk Analysis Division (ERAD) in November. Aimee Hyten is a new member of ERAD's Plant Pests and Protectants Branch. Prior to joining BRS, Aimee spent 5 years with USDA's Agricultural Research Service, where she distinguished herself by receiving the Plant Sciences Institute Technician of the Year award and the Beltsville Agricultural Research Center Technician of the Year Award.

Luc Hebou joined ERAD as a member of the Plants Branch. Luc comes to BRS from the University of Maryland, where he has been working on his PhD and serving as a Graduate Research Assistant. Luc also interned with the USDA-National Agricultural Statistics Service, the U.S. Environmental Protection Agency, and the U.S. Fish and Wildlife Service, and was a public school science teacher. Luc's skills in data collection and analysis and knowledge of computer software applicable to modeling and risk analysis will be a great addition to ERAD. Aimee and Luc provide technical support and analysis for pest risk and environmental risk assessments.

Two new staff members also joined the Resource Management Programs staff in December. Glenn Hunt serves as our new Information Technology Specialist. Prior to this appointment, Glenn worked as a Database Administrator for GSH Associates and also worked with the Risk Management Foundation. Jacquelyn Barnes is a new Program Specialist who will be specializing in personnel and event planning. Prior to joining BRS, Jacquelyn worked for the Department of Commerce/NOAA Executive Office of the Director.

Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting http://jobsearch.usajobs.opm.gov/ and searching for "Biotechnology Regulatory Services" (in quotes).

Have questions about BRS policy and regulations? E-mail us at biotechquery@aphis.usda.gov.

Total Submissions in 2006

Notifications Acknowledged

225	Importation
389	Interstate Movement
305	Environmental Release
685	Combined Interstate Movement/Release

Permits Issued

43	Importation
72	Interstate Movement
63	Environmental Release
405	Courtesy Permits

5 Petitions/Extensions to Grant Non-Regulated Status Received